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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,013	02/21/2002	Arthur Scherf	NIH176.001C1	4025

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,013	SCHERF ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to methods of detecting the concentration or expression level of an FCR3.varCSA gene or protein, classified in class 435, subclass 4.

II. Claim 2, drawn to a methods of making a FCR3.varCSA disease state profile, classified in class 435, subclass 4.

III. Claims 3-11, and 25-27 drawn to nucleic acids encoding FCR3.varCSA or fragments thereof, classified in class 536, subclass 23.1.

IV. Claims 12-21, 24, 32, 33 drawn to the FCR3.varCSA protein and fragments thereof, classified in class 530, subclass 350.

V. Claims 22 and 23, drawn to a method of making a FCR3.varCSA protein by inserting a cDNA encoding such into an expression vector, classified in class 435, subclass 69.1.

VI. Claims 28-31, and claim 47 (in part) drawn to antibodies to the FCR3.varCSA protein or fragments thereof, classified in class 530, subclass 387.1.

VII. Claims 34-36, drawn to methods of identifying FCR3.varCSA dependant adhesion to chondroitin sulfate A, classified in class 435, subclass 4.

VIII. Claims 37-43, drawn to methods of detecting agents that modulate of FCR3.varCSA dependant adhesion to CSA by attaching either CSA or FCR3.varCSA to a support, and contacting the support with either FCR3.varCSA

or CSA, and contacting the support with the agent, classified in class 436, subclass 501.

IX. Claim 44, drawn to methods of identifying an agent that modulates FCR3.varCSA dependant CSA adhesion by contacting a cell transfected with a construct comprising a nucleic acid sequence encoding a protein that binds CSA, classified in class 436, subclass 501.

X. Claim 45, drawn to a method of identifying agents that interact with SEQ ID NO: 2 or a fragment thereof, classified in class 435, subclass 501.

XI. Claim 46, drawn to a method of preparing a therapeutic agent comprising an agent that modulates FCR3.varCSAdependant CSA adhesion and a pharmaceutically acceptable carrier, classified in class 514, subclass 1.

XII. Claim 47, drawn to compositions comprising an agent that modulates FCR3.varCSA dependant CSA adhesion, classified in class 514, subclass 1.

XIII. Claims 48-49, drawn to methods of treating or preventing maternal malaria by administering a nucleic acid complementary to SEQ ID NO: 1 or fragments thereof, classified in class 536, subclass 24.5.

XIV. Claims 50-55, drawn to methods of treating or preventing maternal malaria by administering a FCR3.varCSA protein or fragment thereof, classified in class 514, subclass 1.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if Group I is elected, then election is also required to one of inventions I(A)- I(D)

I(A)- the method involves comparing the concentration level of FCR3.varCSA RNA,
I(B)- the method involves comparing the concentration level of FCR3.varCSA cDNA,
I(C)- the method involves comparing the concentration level of FCR3.varCSA protein, or

I(D)- the method involves comparing the expression levels of FCR3.varCSA genes.

For Group VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-XIV, and, if Group VI is elected, then election is also required to one of inventions VI(A)or VI(B).

VI(A)- an antibody that binds the DBL3 region of FCR3.varCSA, or
VI(B)- an antibody that binds the CIDR1 region of FCR3.varCSA.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I(A)-I(D) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to a different method of detecting the concentration or expression level of an FCR3.varCSA molecule in a subject. Each of these methods has a different mode of operation due to the fact that they are each measuring the presence or activity of a different type of molecule.

3. Inventions VI(A) and VI(B) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these two Groups are drawn to antibodies that bind to different protein sequences. As these antibodies bind to different sequences, they perform different functions, and are therefore distinct. These inventions are linked by claim 28 drawn to antibodies that bind FCR3.varCSA.

4. The inventions a) of Groups III, IV, VI, and XII; b) of Groups V, XI; and c) of Groups I and II, VII, and VIII and IX and X, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions represented by the Groups in each of a), b), and c) each relate to a group of inventions that a) comprise a different type of molecule that performs a different function from the molecules of the other Groups, b) comprise a method of making a molecule not related to the molecule made by the method of the other Group (i.e. the methods perform different functions), and c) comprise a method of identifying or detecting a molecule not detected by the other methods. As the various Groups are not disclosed as usable together, the inventions are distinct.

5. The inventions of Groups IV and III are related as product and process of use with, respectively, the inventions of Groups XIII, and XIV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of using each comprise a method of treating maternal malaria using either the FCR3.varCSA proteins or fragments thereof, or FCR3.varCSA encoding nucleic acids or fragments thereof. However, both the proteins and the nucleic acids may be used in other methods. For example, the protein may be used to produce antibodies, and the nucleic acids may be used to produce the proteins. Thus, the inventions of Groups XIII, and XIV are distinct from the inventions of Groups IV and III.

6. Inventions V and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein may be either isolated from nature, or recombinantly made through the claimed process.

As the protein may be had through multiple processes, it is distinct from the method of making it.

Conclusion

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

8. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

9. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to

> final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
February 3, 2003

JAMES HOUSEL 2/10/03
SUPERVISORY PATENT EXAMINER
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